

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/L2005/000255

International filing date (day/month/year)
03.03.2005

Priority date (day/month/year)
04.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61N1/30

Applicant
HADASIT MEDICAL RESEARCH SERVICES & DEVELOPMENT...

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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10/591124

International application No.
PCT/IL2005/000255**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Re Item III.

Claims 14-17 refer to therapeutic methods of treatment practised on the human or animal body. According to the PCT neither search (Rule 39.1 (iv) PCT) nor examination (Rule 67.1 (iv) PCT) is required for such subject-matter.

Re Item V.

1. Reference is made to the following document:
D1: US 2003/018295 A1 (HENLEY JULIAN L ET AL) 23 January 2003 (2003-01-23)
D2: US 2001/023330 A1 (PALTI YORAM) 20 September 2001 (2001-09-20)
D3: US-A-5 383 848 (HILLMAN ET AL) 24 January 1995 (1995-01-24)
D4: US R E38 341 E1 (HENLEY JULIAN L [US]) 9 December 2003 (2003-12-09)
D5: US 2002/115957 A1 (SUN YING ET AL) 22 August 2002 (2002-08-22)

2. Claims 1-4, 7-10 and 13:

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses:

A device for iontophoretic delivery of a drug to or into a tissue (par. 3), comprising an arrangement that prevents operation of the device at a current density that is higher than a predetermined value, said arrangement including first means responsive to a first data item, indicative of the surface area through which the current is to pass, as to set the maximal current allowed at the surface area indicated by said data item (par. 27).

Also documents D2-D4 disclose the subject-matter of claim 1.

- 2.2 Dependent claims 2-4, 7-10, 13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

3. Claims 5, 6, 11, 12 and 18-24:

The prior art (D5) discloses a sponge (par. 50, 61, fig. 6 (618)) having a data transmitting module (par. 87, fig. 6 (622)), but fails to disclose a data transmission indicative of the sponge's size and/or surface area of contact of the sponge with the tissue.

Thus, the subject-matter of claims 5, 6, 11, 12 and 18-24 is novel (Article 33(2) PCT).

The problem solved by the invention is:

- How to avoid skin burns in the contact area of an iontophoretic device.

This problem has been addressed in several prior art document, some of which also take the surface of the sponge (or corresponding part) into account. However, no prior art document suggests transmitting this information from the sponge to the current control circuit.

Thus, the subject-matter of claims 5, 6, 11, 12 and 18-24 involves an inventive step.

4. When filing amended claims the applicant should consider the following:

- 4.1 The applicant should indicate the **difference** of the subject-matter of the new claim vis-à-vis the state of the art (in particular with regard to D1-D5) and the significance thereof, i.e. the underlying **technical problem** which those features of the independent claim which form a contribution over the prior art solve in an inventive way. In the letter of reply, the applicant could apply the **problem-solution approach** for inventive step as outlined in the PCT International Search and Preliminary Examination Guidelines, Part III, Appendix to Chapter 13, A13.08.1-9.
- 4.2 The applicant should bring the description into conformity with the amended claims. Care should be taken during revision not to add subject-matter which extends beyond the content of the application as originally filed (Article 19(2) and 34(2)(b) PCT).
- 4.3 The applicant should, in order to facilitate the examination of the conformity of the

amended application with the requirements of Article 19(2) and 34(2)(b) PCT, identify clearly all amendments made, irrespective of whether they concern amendments by addition, replacement or deletion and indicate exactly on which passages of the original application these amendments are based (Rule 66.8 PCT (see also the PCT International Search and Preliminary Examination Guidelines, Part VI, Chapter 20.06-07)).

Re Item VII.

1. The relevant background art should be mentioned in the description, and the corresponding document should be identified therein (Rule 5.1(a)(ii) PCT).
2. The independent claims should be in the two-part form according to Rule 6.3(b) PCT, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
3. The features of the claims should be provided with reference signs placed in parentheses (Rule 6.2(b) PCT).